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ABSTRACT

This study is a randomized controlled trial to investigate the feasibility and effectiveness of a brief Anxiety Reduction Treatment for Acute Trauma (ARTAT) with adults (over age 18) showing signs of peritraumatic anxiety in the Emergency Department of Bellevue Hospital, New York in the hours following a psychologically traumatic event. Thirty-six participants will be enrolled over a 12-month period (18 receiving ARTAT and 18 receiving Treatment As Usual (TAU). The study will target anxious arousal in patients immediately (1 to 8 hours) following a trauma. Participants will be recruited from among patients who present in the Emergency Department at Bellevue Hospital for treatment of an injury sustained in a traumatic event (accident, assault) as long as injuries do not preclude participation. Participants included in the study will have experienced a trauma within 8 hours and presenting with signs of a strong risk factor for PTSD: peritraumatic panic (severe psychological and physiological anxiety symptoms such as fear of dying, fear of losing emotional control, tachycardia, sweating, shaking and dissociation symptoms such as derealisation and depersonalization that occur during and immediately following a trauma. Following the initial assessment, eligible participants will be randomized to receive the one-hour anxiety-reduction intervention designed to reduce anxiety and panic symptoms through education and anxiety management skills or the TAU. The clinician administered and self-report assessments will be administered at screening, baseline, post-treatment, and at a one-month and three-month follow-up.

INTRODUCTION

The purpose of the proposed research is to pilot a behavioral intervention specifically designed to reduce the symptoms of peritraumatic panic, in order to reduce the likelihood of subsequent PTSD. We have developed the Anxiety Reduction Treatment for Acute Trauma (ARTAT), a one-session intervention targeting at-risk individuals (those continuing to experience peritraumatic panic following a trauma) and enhance self-efficacy. The intervention provides education about common responses to trauma in order to normalize symptoms and teaches individuals anxiety management techniques such as deep breathing and muscle relaxation. ARTAT specifically avoids encouraging people to process the trauma (given evidence that this may enhance arousal). There is evidence that this type of anxiety management approach is effective in treating panic disorder and in ameliorating symptoms of chronic PTSD, and such tools are likely to be seen by participants as useful, empowering, and a non-stigmatizing way to cope with the common reactions to trauma.

This study is a randomized controlled trial of a single session 60- minute Anxiety Reduction Treatment for Acute Trauma (ARTAT) administered during Emergency Department (ED) admission to patients presenting with anxiety following traumatic exposure. Thirty-six participants will be enrolled over a 12-month period (18 receiving ARTAT and 18 receiving Treatment As Usual (TAU)). The study will target anxious arousal in patients immediately (1 to 8 hours) following a trauma. Participants will be recruited from among patients who present in the Bellevue Emergency Department for treatment of an injury sustained in a traumatic event (accident, assault) as long as injuries do not preclude participation. Participants included in the study will have experienced a trauma within 8 hours and presenting with signs of a strong risk factor for PTSD: peritraumatic panic (severe psychological and physiological anxiety symptoms such as fear of dying, fear of losing emotional control, tachycardia, sweating, shaking and dissociation symptoms such as derealisation and depersonalization that occur during and immediately following a trauma. Following the initial assessment, eligible participants will be randomized to receive the one-hour anxiety-reduction intervention designed to reduce anxiety and panic symptoms through education and anxiety management skills or the TAU. The clinician administered and self-report assessments will be administered at screening, baseline, post-treatment, and at a one-month and three-month follow-up.

If ARTAT is successful at preventing PTSD symptoms in civilians, it will be modified for military personnel with persistent emotional distress immediately following combat operations. The aim will be to increase resilience for current mission operations, increase readiness for future deployments, and prevent occupational/social disability and stress related physical health problems associated with combat related PTSD. It is hypothesized that: (1) ARTAT will result in significantly decreased anxious arousal immediately following the intervention and (2) Reduction in anxiety following the intervention will be

associated with fewer acute distress disorder (ASD) and PTSD symptoms at follow-up.

Primary Aims:

1. To manualize a cognitive-behavior therapy (CBT) based behavioral intervention for adults experiencing peritraumatic anxiety in the immediate aftermath of a traumatic event.
2. To conduct a randomized controlled trial in a New York City emergency department setting with 18 patients receiving ARTAT and 18 patients receiving Treatment As Usual (TAU)
3. To determine if ARTAT results in immediate anxiety reduction in the ED
4. To determine if anxiety reduction in the ED predicts lower levels of PTSD symptoms at one month and three months.

BODY: KEY RESEARCH ACCOMPLISHMENTS

As mentioned in the final report submitted through NCIRE on 3/5/10, this grant has gone through a major transition over the course of 2009-2010. To summarize, this grant was awarded to Dr. Marmar while he was working as Professor, and Vice Chair of Psychiatry at the San Francisco VAMC/University of California, San Francisco (UCSF). In November of 2009 we received IRB approval from both the Committee at UCSF and the SFVA. On November 30, 2009 we received confirmation that the IRB documents were submitted for review with the DOD. While this grant was awarded, we made significant progress toward achieving the first objective described in the Scope of Work: To manualize the CBT based behavioral intervention and complete programmatic pre-launch infrastructure, first in San Francisco and now in NYC. While in San Francisco, the staff prepared to work on the project included the project coordinator and research assistant. The IRB approval within the UCSF and SFVAMC took several submissions to obtain final approval. In addition, the staff met with the San Francisco General Hospital (SFGH) Emergency Department Staff to finalize recruitment procedures. Lastly, an application for a no-cost extension was granted in November of 2009.

In December of 2009 Dr. Marmar transitioned to a new position as Chair of the Department of Psychiatry at New York University Medical Center (NYUMC). Hence, the effort and focus has been on relinquishment of this grant from the DOD and Northern California Institute for Research and Education (NCIRE) and the transfer of this grant to NYU. The process to transfer this grant entailed several meetings with NCIRE and NYU contracts and grants specialists, reworking the budget and budget justification for NYU and resubmitting all documentation to NYU and the DOD for final approval of the transfer of this grant. The grant has been successfully transferred to NYU. In addition, the Principal Investigator and Co-Investigator, Dr. Henn-Haase met with the Emergency Department personnel to establish networks to accomplish this study through Bellevue Hospital.

Tremendous progress has been made since transferring the grant to NYU. Several personnel have been hired and trained to work on the grant and includes the postdoctoral fellow who will assist with project management and administering the clinical intervention, the research assistant, project manager, and we have a few candidates to help with the daytime on-call clinical responsibilities. We are in the process of posting and interviewing potential candidates for project management and on-call clinical staff to provide services after hours. We have submitted and received IRB approval from both NYU and Bellevue Hospital on August 3rd and submitted the protocol to the DOD on August 5th for final approval. Since hiring personnel, we have scheduled weekly meetings to move forward with finalizing the adaptation of procedures to Bellevue ED and preparing to establish a secure tracking database and data infrastructure to download all pertinent data for analyses.

We aim to launch this study the end of September, pending the DOD approval. The tasks to complete in preparation for running the first participant include: hiring and training the project coordinator, and the evening/weekend on-call clinicians. We will need to make modifications to the Federal Certificate of Confidentiality. Although we are not fully staffed, we feel prepared to begin recruiting for the study by the end of September and upon DOD IRB approval. Our goal is to complete the pilot intervention over the course of six months followed by data preparation and analyses for manuscript publication and the determination of future grant proposals.

CONCLUSIONS

The grant has been relinquished from the contracts and grants department through the Northern California Institute of Research and Education (NCIRE) to the DOD and the final documents were submitted to the DOD for the award transfer to NYU. The grant has officially been transferred to NYU. The transfer of this grant entailed a focus on administrative duties to relinquish and transfer the grant to NYU. This has entailed several meetings with contracts specialists from both NCIRE and NYU in an effort to develop a smooth transition of this study. The protocol was submitted to the DOD for final approval on August 5, 2010. Lastly, the study personnel have worked diligently to meet with the Emergency Department personnel at Bellevue Hospital to establish a working relationship and to obtain approval to run this study successfully within their ED. Several meetings were held to revise the procedures and IRB materials in order to meet the demands of working within a new medical system. The working relationship established with Bellevue ED personnel has been very positive and we feel confident that we can expedite this study upon IRB approval in an effort to complete the data collection within the next year. We have hired and trained several personnel, have been attending weekly study meetings and in the process of hiring the remainder of the staff. Our goal is to hire the after-hours on-call clinicians, and train the clinical staff, finalize procedures, and develop the databases in preparation to launch the study the end of September 2010. We feel confident that we can complete the study over the course of this next year. The transfer of this grant to NYU Medical Center/Bellvue Hospital has given us increased confidence that we will be able to test the hypotheses for the efficacy of a brief anxiety reduction treatment in the Emergency Department as proof of concept to use in the combat zone with military personnel. Not only have we received more support from this study since transferring to NYU and Bellevue's ED, but we have access to a much larger pool of potential participants with the full cooperation and support of Bellevue's ED Director.

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APPENDIX

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